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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,696	03/25/2004	Gudmundur Johannsson	31611-5A	6059

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DINSMORE & SHOHL, LLP  
1900 CHEMED CENTER  
255 EAST FIFTH STREET  
CINCINNATI, OH 45202

EXAMINER

MOHAMED, ABDEL A

ART UNIT PAPER NUMBER

1653

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/808,696	Applicant(s) JOHANSSON ET AL.	
	Examiner Abdel A. Mohamed	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 11-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **ACKNOWLEDGMENT TO AMENDMENT, REMARKS, DECLARATION AND STATUS TO THE CLAIMS**

1. The amendment, remarks and the copy of the Declaration under 37 C.F.R. 1.132 which was originally submitted in parent application Serial No. 09/050,366 filed 03/10/05 are acknowledged, entered and considered. In view of Applicant's request claims 11 and 12 have been amended and claim 19 has been added. Claims 11-19 are now pending in the application. The objection to the Title and the rejections under 35 U.S.C. 112, first paragraph and 35 U.S.C. 112, second paragraph are withdrawn in view of Applicant's amendment and remarks. However, the rejection under 35 U.S.C. 103(a) over the prior art of record is maintained.

### **CLAIM REJECTIONS-35 U.S.C. § 103(a)**

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-18 including newly submitted claim 19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Johansson et al (Metabolism, Vol. 44, No. 9, pp. 1126-1129, September 1995) taken with Rosen et al (Acta Endocrinologia, Vol. 129, pp. 195-200, 1993) and Reaven et al (N. eng. J. Med., Vol. 334, No. 6, pp. 374-381, 1996).

Applicant's arguments filed 03/10/05 have been fully considered but they are not persuasive. Applicant has argued that the primary reference of Johansson et al is directed to insulin resistance of adult patients who are growth hormone deficient. Also, Dr. Werner's Declaration states that growth hormone deficient patients are distinct from patients who are not growth hormone deficient. Specifically, growth hormone deficient patients do not produce growth hormones and therefore their hormone levels and their therapeutic responses to growth hormone administration differ significantly from the hormone levels and therapeutic response to growth hormone administration in a patient who is not growth hormone deficient is noted. However, contrary to Applicant's

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arguments independent claim 11 is directed to "A method for treating a patient having metabolic syndrome comprising primary insulin resistance....., wherein said method comprises administering to said patient **human growth hormone or an analog thereof**..... ". Therefore, the limitations Applicant argued with (i.e., adult patients who are growth hormone deficient) are not recited in the rejected claim(s). Further, the claim language "comprising" which would not exclude administering a patient other type of human growth hormone, namely human growth hormone deficient, in view of the statement above, the claim contemplates administering to a patient **any type of human growth hormone or an analog thereof**, which would clearly encompass administering to patients who are growth hormone deficient. Therefore, Applicant's arguments and the declaration provided therewith are not commensurate to the scope of the claims. Accordingly, the combined teachings of the prior art make *prima facie* obvious the claimed invention for the reasons of record.

### **ACTION IS FINAL**

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

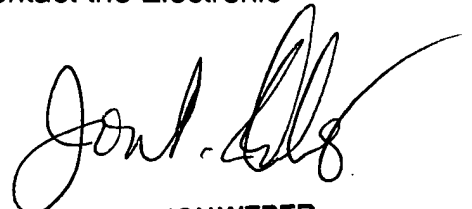
### CONCLUSION AND FUTURE CORRESPONDANCE

4. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272 0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
JON WEBER  
SUPERVISORY PATENT EXAMINER

*AAM* Mohamed/AAM  
May 26, 2005